Supreme Court, U.S.
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No. 03-1586

IN THE

Supreme Court of the United States

ANDREW BOURNE, a minor by and through his parents, next friends and natural guardians, CHRIS BOURNE and MAGGIE BOURNE,
Petitioner,

v.

E.I. DUPONT DE NEMOURS & COMPANY,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Fourth Circuit correctly affirmed the district court's decision to exclude expert testimony where that testimony was based on speculative extrapolations from *in vivo* and *in vitro* studies that failed to meet the reliability and relevance standards under Federal Rule of Evidence 702.

CORPORATE DISCLOSURE STATEMENT PURSUANT TO RULE 29.6

Respondent E.I. du Pont de Nemours and Company ("DuPont") has no parent company, and no publicly held company owns 10% or more of DuPont's stock. DuPont is a publicly traded corporation listed on the New York Stock Exchange.

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IN THE

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E.I. DUPONT DE NEMOURS & COMPANY,
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RESPONDENT'S BRIEF IN OPPOSITION

STATEMENT OF THE CASE

This is a products liability case in which Petitioner Andrew Bourne alleges that his ocular and other birth defects were caused by his mother's dermal exposure to Benlate while she was pregnant. Benlate is a plant fungicide manufactured by DuPont and sold worldwide for more than 30 years.

Pursuant to Federal Rule of Evidence 702, DuPont moved to exclude the testimony of Petitioner's causation experts, Drs. Howard and Tackett. DuPont explained that Drs. Howard's and Tackett's asserted methodology for determining the human teratogenicity of a substance was specula-

tive, scientifically invalid, unreliable, and not relevant. Following briefing, and agreement by the parties that the record was complete and a hearing was not needed, the district court granted DuPont's motion without a hearing.

In a Memorandum Order dated January 11, 2002, the district court held that Petitioner's experts' method of attempting to extrapolate causation of human birth defects from single-species, high dose gavage animal (rat) and *in vitro* (cell culture) studies was neither reliable nor relevant. Petitioner then requested, without objection from DuPont, that the evidentiary deposition of an epidemiologist, Dr. Ozonoff—another designated expert of Petitioner—be made a part of the record and considered by the court. After granting Petitioner's request and considering Dr. Ozonoff's testimony,[1] the district court reissued its Memorandum Order, revised in minor respects to reflect its further consideration of Dr. Ozonoff's testimony, and granted DuPont's motion to exclude on the same basis set forth in its original order. *See Bourne v. E.I. DuPont de Nemours & Co.*, 189 F. Supp. 2d 482, 496-501 (S.D.W. Va. 2002), Pet. App. at 71-84. Absent proof of causation for Petitioner's claim, the district court granted DuPont's motion for summary judgment and dismissed the case.

Petitioner appealed to the United States Court of Appeals for the Fourth Circuit. The court of appeals concluded that in "excluding the proffered testimony, the district court properly exercised its 'gate-keeper' function by focusing on the methodology employed by the expert rather than the conclusions they reached . . . we can not say that the district court abused its discretion." *See Bourne v. E.I. DuPont de Nemours*, No. 02-1469, slip op. at 6 (4th Cir. Jan. 27, 2004)

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[1] As the January 11, 2002, order reflects, the district court had already considered Dr. Ozonoff's views (based on an earlier discovery deposition). *See* January 11, 2002 Memorandum Order at 21-23.

(*per curium*), Pet. App. at 7. On that basis the Fourth Circuit affirmed the decision of the district court excluding the testimony of Drs. Howard and Tackett. *Id.* Petitioner filed a petition for rehearing which was denied on February 23, 2004.

This petition followed.

REASONS FOR DENYING WRIT

The Court should decline to grant the petition for a writ of certiorari. The district court properly exercised its "gatekeeper" function in finding that the Petitioner's experts' proposed method of extrapolation of human teratogenicity from single-species, high dosage gavage rat tests and *in vitro* tests was unreliable and lacked "fit." This case does not present the question that Petitioner advertises—even assuming that such a question would warrant certiorari. Contrary to Petitioner's assertions, the court of appeals' decision does not require "positive" epidemiology as a basis for expert opinion testimony concerning causation in a toxic tort case. Even if the court of appeals had required "positive" epidemiology in this case, such a holding would not conflict with the decisions of other federal courts of appeal in *teratology* cases.

I. THE DISTRICT COURT PROPERLY EXERCISED ITS "GATEKEEPER" FUNCTION IN FINDING THE PROPOSED METHOD OF EXTRAPOLATION OF HUMAN TERATOGENICITY FROM SINGLE-SPECIES, HIGH DOSAGE GAVAGE RAT TESTS AND *IN VITRO* TESTS UNRELIABLE AND LACKING IN "FIT".

As the district court observed, "Drs. Howard and Tackett have derived their general causation theory, that benomyl is teratogenic to humans, based solely upon *in vivo* rat gavage studies and *in vitro* tests." *Bourne*, 189 F. Supp. 2d at 495, Pet. App. at 71. The district court then identified the scien-

tific and factual shortcomings of the methodology that they had used. These included:

- Significant differences between species in teratogenic response to chemicals. *Id.* at 496–97, Pet. App. 73–75.
- Petitioner's experts' disavowal of and inability to explain the results of benomyl tests on two other animal species—rabbit and mouse—that showed no ocular birth defects in the offspring. *Id.* at 496–97, Pet. App. at 73–75.
- The absence of tests on species closely related to humans. *Id.* at 496–97, Pet. App. at 72-75.
- The use of high dosages in the rat tests, far in excess of human exposures. *Id.* at 498-99, Pet. App. at 76-78.
- *In vitro* test exposures at high levels for 24 hours, far in excess of human exposures. *Id.* at 498-99, Pet. App. at 76-78.
- A mode of exposure, direct injection into the stomachs of rats, unlike the human dermal exposure that was at issue in this case. *Id.* at 498-500, Pet. App. at 76-83.
- Petitioner's experts' unfounded rejection of human data contrary to their position. *Id.* at 493, 495, 497, Pet. App. at 72-73, 75-77, 80-83.

The district court discussed the fact that teratologists (and other courts) have rejected *in vivo* animal and *in vitro* tests as a basis for finding human teratogenicity in birth defect cases.[2]

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[2] *See also* Anthony R. Scialli, *A Clinical Guide to Reproductive and Developmental Toxicity* at 60-61 (1992) (teratologists do not accept positive results in animal tests as proof of human teratogenicity because there are (1) species differences in the pharmacokinetics/handling of chemicals (difference in absorption, distribution, metabolism, elimination); (2) species differences in fetal and embryo susceptibility, and (3) differences in

Id. at 496-97, Pet. App. at 73-77. This analysis of the facts, science, and law relating to the methodology employed by Petitioner's experts—extrapolation of human teratogenicity from single-species, high dosage gavage animal tests and *in vitro* tests—is precisely the kind of "gate-keeping" contemplated by this Court's *Daubert* decision. The court of appeals opinion recognizes that the district court's "well-reasoned opinion" reflects the type of "gate-keeping" that this Court's decisions mandate. *See Bourne*, slip. op. at 6, Pet. App. at 7.

II. THE PETITION INCORRECTLY ASSERTS THAT THE COURT OF APPEALS CREATED A RULE REQUIRING EPIDEMIOLOGY TO BE THE BASIS FOR EXPERT OPINION TESTIMONY CONCERNING CAUSATION IN TOXIC TORT CASES.

Petitioner asserts that this case presents the question "whether *Daubert* requires positive epidemiology to support a finding of causation in a toxic tort case." Petition at 7. That assertion misstates the holdings of both the district court and the court of appeals. Neither court held that epidemiological evidence was a prerequisite to expert opinion testimony on causation in such cases.

The district court did not require epidemiological evidence as a basis of expert opinion testimony offered as proof of causation in this case. Rather, the district court focused on the specific methodology employed by Drs. Howard and Tackett—extrapolation of human teratogenicity from rat gavage tests and extrapolation of human teratogenic dose levels from *in vitro* cell tests—and held that such extrapolation was unreliable and irrelevant. *Bourne*, 189 F. Supp. 2d at 496, 497-54 (Pet. App. 72, 73-84). Epidemiological evi-

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the dose and route of exposure (*e.g.*, gavage v. dermal) as between humans and laboratory test animals).

dence would present a way of bridging the gap the court correctly saw in Petitioner's methodology in assessing causation, but nowhere did it hold that epidemiology was mandated. It held that what was presented by Petitioner's experts was not acceptable because it was unreliable and irrelevant. The court of appeals, without referring to epidemiology at all, approved the district court opinion as "well reasoned" and held that that "the district court properly exercised its 'gate-keeper' function by focusing on the methodology employed by the experts rather than the conclusion they reached." *Bourne*, slip. op. at 6, Pet. App. at 7.[3]

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[3] While it was not the basis for the district court's exclusion of Drs. Howard's and Tackett's opinion testimony or the basis for the court of appeals' decision affirming that exclusion, the absence of any human evidence of Benlate teratogenicity reflects a major methodological failure in the derivation of Petitioner's experts' opinions. The generally accepted, peer reviewed, methodology employed by clinical teratologists requires positive human studies to establish human teratogenicity of a substance, as numerous trial courts have recognized. *See Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1451 (D.V.I.), *aff'd*, 46 F.3d 1120 (3d Cir. 1994); *National Bank of Commerce v. Dow Chem. Co.*, 965 F. Supp. 1490, 1497 n. 14, 1499-1500 (E.D. Ark. 1996), *aff'd*, 133 F.3d 1132 (8th Cir. 1998); *DePyper v. Navarro*, No. 83-303467-NM, 1995 WL 788828, at *32 (Mich. Cir. Ct. Nov. 27, 1995), *aff'd*, No. 191949, 1998 WL 1988927 (Mich. Nov. 6, 1999); *Oxendine v. Merrell Dow Pharms., Inc.*, No. 82-1245, 1996 WL 680992, at *7 (D.C. Super. Ct. Oct. 24, 1996).

Daubert and *Kumho* establish that, in assessing the reliability of expert testimony, a trial court should look to the principles of the discipline or field in which the opinion is being offered. *Kumho Tire Co. v. Carmichel*, 526 U.S. 137, 152 (1999); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591-95 (1993); *see also Cavallo v. Star Enterprise*, 100 F.3d 1150, 1159 (4th Cir. 1996) (*Daubert* factors "require that the methodology and reasoning used by a witness have a significant place in the discourse of experts in the field.") The field of teratology requires epidemiology for a determination that a substance is a human teratogen. *See, e.g.*, Thomas H. Shepard, *"Proof" of Human Teratogenicity*, Teratology 50: 97-98 (1994); Thomas H. Shepard, *Catalog of Teratogenic Agents* at xxiv (10th

The Petition does not address the actual holding of the court of appeals or the holdings of the district court which were affirmed by the court of appeals. Nor does the Petition state a question for review that arises from those decisions. The lack of connection between the arguments of Petitioner and the holdings of the courts below is apparent from the following comparison:

Petitioner's Argument As To What The District Court and Court of Appeals Held	Actual District Court Holdings Affirmed By The Court Of Appeals
"Nonetheless, the principal reason the District Court excluded the testimony of Drs. Howard and Tackett was their reliance on Dr. Ozonoff's conclusion that these epidemiological studies were flawed and irrelevant." (Petition at 8)	"[T]he extrapolations of Drs. Howard and Tackett, from high-dosage, single species *in vivo* testing and lengthy benomyl exposure *in vitro* testing, to conclude that benomyl is a human teratogen and to establish the levels at which it is alleged to be teratogenic, are neither reliable, pursuant to the first prong of Daubert, nor relevant, under the second prong."
"[Y]et the District Court used Ozonoff's analysis of the existing Benlate epidemiology as the primary	

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ed. 2001); James L. Schardein, *Chemically Induced Birth Defects*, at 43-44 (3d ed. Rev. 2000), quoting Thomas H. Shepard, *Catalog of Teratogenic Agents* (8th ed. 1998); Robert L. Brent, *Utilization of Animal Studies to Determine the Effects and Human Risks of Environmental Toxicants (Drugs, Chemicals, and Physical Agents)*, Pediatrics 113:984, 987 (2004). If the district court and the court of appeals had recognized such a requirement for expert testimony on the human teratogenicity of a substance, that ruling would have been correct and would not have been an abuse of discretion. The lower courts in this case did not, however, reach that issue and they need not have done so. It was a sufficient basis for their decisions that they examined the methodology in fact used by Drs. Howard and Tackett, rejecting it as unreliable and irrelevant.

basis to exclude Howard and Tackett's testimony." (Petition at 13)

"But in affirming the District Court's decision, the Fourth Circuit, . . . implicitly overruled its own earlier decisions holding that epidemiological support was not a prerequisite to establishing causation in toxic tort cases." (Petition at 7)

(*Bourne*, 189 F. Supp. 2d at 496, Pet. App. at 72)

"The court concludes that Drs. Howard and Tackett have failed to offer sufficient support for the otherwise suspect single species *in vivo* tests and *in vitro* tests to render methodologically sound an extrapolation of human teratogenicity." (*Bourne*, 189 F. Supp. 2d at 497-98, Pet. App. at 76)

"Moreover, the rat gavage studies and the *in vitro* tests relied upon by Drs. Howard and Tackett, using injections of high-levels of benomyl directly into the stomach of rats and high-level *in vitro* dosing of cells of both rats and humans in benomyl for 24 hours, do not 'fit' with the facts of the case as alleged." (*Bourne*, 189 F. Supp. 2d at 498, Pet. App. at 76)

The district court, in arriving at its conclusions, discussed some of the reasons that teratologists do not accept extrapolation of human teratogenicity from animal and *in vitro* tests. *See Bourne*, 189 F. Supp. 2d at 496-98, Pet. App. at 72-77; *see also* discussion, *supra*, at 3-4. In the context of that discussion, the district court noted as well that, "in the

absence of other strong indicators of the reliability of *in vivo* and *in vitro* tests, including supporting epidemiological studies, testing on closely related species, and the use of comparable dosages, courts have overwhelmingly found unreliable the methodology of extrapolating human teratogenicity from *in vivo* and *in vitro* tests." *Bourne*, 189 F. Supp. 2d at 496, Pet. App. at 73. In other words, the court properly recognized that the type of testing done here involving ultra-high doses given to rats by gavage, is not generally accepted as a basis for extrapolating human teratogenicity under the standards of the relevant discipline. Rather, teratologists require additional indicia of reliability, including epidemiology. *See supra* notes 2 and 3. The district court's factual observations that teratologists and other courts reject extrapolation of human teratogenicity from single-species, high dosage gavage animal tests and *in vitro* tests are not holdings by the district court that epidemiology is an essential basis for expert opinion offered to prove causation in a case involving toxic torts; they are recognition that such extrapolation is not generally accepted in the field of teratology. Significantly, Petitioner cites no case under *Daubert* and Rule 702 challenging the court's observation that other courts, like teratologists, do not accept such extrapolation.

Nor was the district court's additional observation that the existing Benlate epidemiological evidence is contrary to Petitioner's position, (*id.* at 497 & n.23, Pet. App. at 75 & n.23), a holding that epidemiology is affirmatively required to demonstrate causation.[4]

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[4] The district court's determination that Drs. Howard's and Tackett's rejection of Benlate epidemiological studies—which find no association between Benlate exposure and birth defects—was unfounded, *Bourne*, 189 F. Supp. 2d at 493, Pet. App. 30, does not constitute a holding by the district court that epidemiology is a prerequisite to proof of causation. The district court ruling that Drs. Howard's and Tackett's rejection of epidemiology that is contrary to their position is unfounded—the sole focus of the Petition—is irrelevant to whether Petitioner's experts could

The court of appeals' affirmance of the district court's actual holdings does not convert these separate factual observations by the district court into rulings by the court of appeals that epidemiology is a prerequisite to opinion testimony on causation in toxic tort cases. Petitioner has mischaracterized the basis for the district court's holding on the unreliability and lack of "fit" of Drs. Howard's and Tackett's methodology. The Petition ignores the fact that the opinion of the court of appeals says nothing, explicitly or implicitly, about the place of epidemiology in proving causation in toxic tort cases. Petitioner's stated questions for review do not arise from and are unrelated to the court of appeals decision in this case.

III. THERE IS NO CONFLICT BETWEEN THE DECISION OF THE COURT OF APPEALS IN THIS CASE AND ANY OTHER CIRCUIT.

There is no circuit conflict.

First, the court of appeals' decision in this case does not require that expert testimony concerning causation in toxic tort cases be based on "positive" epidemiology. The appellate opinion says nothing on that subject. Nor does its affirmance of the district court decision implicitly or "effectively" suggest that result as Petitioner argues. The district court decision excluding the testimony of Drs. Howard and Tackett is based on the fact that their methodology—extrapolation of human teratogenicity from single-species, high dosage gavage animal tests and *in vitro* tests—is unreliable and irrelevant; it is not based on the failure of the experts in this case to rely on "positive" epidemiology. The opinion of the district court does not say or imply that the court is requiring

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properly extrapolate human teratogenicity from rat and *in vitro* tests. Such extrapolation is not a reliable methodology in the field of teratology and the district court properly so held. *See id.* at 497 n.21, Pet. App. at 75 n.21.

experts to base their opinions on "positive" epidemiology in order to prove causation in toxic tort cases. The court of appeals decision cannot, therefore, be in conflict with decisions of other circuits regarding lack of need for "positive" epidemiology in some toxic tort cases.

Second, even if the Fourth Circuit had required "positive" epidemiology, such a holding would not conflict with the decisions of other federal courts of appeal in *teratology* cases. In evaluating the circuit conflict issue that Petitioner seeks to raise, it is important to distinguish teratology cases from other toxic tort cases. Some fields of science or medicine involved in other toxic torts may not in fact rely heavily or at all on epidemiology.[5] That is not the case with respect to teratology. The generally accepted methodology for determining human teratogenicity of a substance involves: (1) identifying a specific pattern of malformation associated with exposure to the substance; (2) consistent human studies (epidemiology) and occurrence of the specific pattern of malformation; (3) repeated positive animal tests in multiple species at doses and routes of exposure similar to those involved in human exposures; (4) *in vitro* tests identifying a mechanism of action; and (5) biological plausibility that the agent's mechanism of action could cause the pattern of defects associated with exposure.[6]

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[5] *See, e.g., Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995) (where issue was whether liver damage was caused by Tylenol/alcohol consumption or by herpes, epidemiology was unnecessary and a methodology consisting of identifying a history of Tylenol/alcohol use, laboratory tests showing presence of Tylenol in blood, and microscopic examination of liver tissue samples to confirm whether tissue damage was or was not characteristic of damage caused by Tylenol was acceptable for diagnostic purposes concerning causation).

[6] *See* Thomas H. Shepard, *"Proof" of Human Teratogenicity*, Teratology 50:97-98 (1994); Thomas H. Shepard, *Catalog of Teratogenic Agents* at xxiv (10th ed. 2001); Robert L. Brent, *Utilization of Animal Studies to Determine the Effects and Human Risks of Environmental*

The case law of the various circuits is uniform in acknowledging that epidemiology is an essential basis for expert opinion testimony concerning causation in *teratology* cases.[7] Thus, even if the Fourth Circuit decision in this case were interpreted to require that expert opinion in the field of teratology be supported in part by epidemiology, that interpretation would create no conflict among the circuits.

Third, none of the cases cited by Petitioner demonstrate any controversy about the role of epidemiology in *teratology* cases. With two exceptions, those cases do not involve expert testimony in the field of teratology. One exception is *Ambrosini*.[8] While it is a teratology case, it provides Petitioner no support for his argument that there is a conflict in the circuits. In *Ambrosini*, there was "positive" epidemiology indicating an association between the type of drug involved, a progestin, and birth defects; the plaintiff's expert so asserted in an affidavit filed in opposition to a motion for

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Toxicants (Drugs, Chemicals, and Physical Agents), Pediatrics 103:984, 987 (2004); James L. Schardein, *Chemically Induced Birth* Defects at 44 (3d ed. Rev. 2000); Anthony R. Scialli, *A Clinical Guide to Reproductive and Developmental Toxicology* at 60, 65, 84 (1992); James C. Wilson, *Embryotoxicity of Drugs in Man, in the Handbook of Teratology* at 311-12 (1977) (James C. Wilson and F. Clarke Fraser, eds.); *Wade-Greaux, Inc.*, 874 F. Supp. at 1450-55; *National Bank of Commerce v. Dow Chem. Co.*, 965 F. Supp. at 1497 n. 14, 1499-1500; *see also* cases cited in note 7, *infra*.

[7] *See Raynor v. Merrell Pharm, Inc.*, 104 F.3d 1371, 1375 (D.C. Cir. 1997); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1321 (9th Cir. 1995) (Daubert II); *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990); *Wilson v. Merrell Dow Pharm.*, 893 F.2d 1149, 1154 (10th Cir. 1990); *Brock v. Merrell Dow Pharm., Inc.*, 874 F.2d 307, 313 (5th Cir.), *modified on reh'g*, 884 F.2d 166 (1989); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 830-31 (D.C. Cir. 1988); *Lynch v. Merrell-National Lab.*, 830 F.2d 1190 (1st Cir. 1987); *cf. Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1071 (6th Cir. 1993); *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992).

[8] *Ambrosini v. Labaraque*, 101 F.3d 129 (D.C. Cir 1996).

summary judgment.[9] *Ambrosini* specifically relied on the fact the plaintiff experts had based their conclusions concerning causation of birth defects on "human" (epidemiological) evidence.[10] Thus, anything the *Ambrosini* court may have said about the lack of necessity for epidemiology[11] was *dicta* unrelated to the decision in the case. Indeed, in *Ambrosini* the D.C. Circuit discussed its prior *Richardson* decision with approval.[12] That case held that animal tests, *in vitro* tests, and recalculated epidemiology studies that are at odds with the underlying epidemiology studies are not relied on by experts in the field of teratology.

The only other teratology case cited by Petitioner to suggest a conflict in the circuits, *Turpin*, is not about "positive" epidemiology or about failure of plaintiff experts to rely on "positive" epidemiology to prove causation in a teratology case.[13] The epidemiology in that case was 35 negative studies relied on by defendant to demonstrate no causal relation between the drug Bendectin and birth defects. *Turpin* did not hold that plaintiff experts need not rely on epidemiology; rather, *Turpin* held that defendant's epidemiology studies in that case were not so conclusive that they warranted grant of summary judgment for defendant.[14]

The Fourth Circuit has not yet addressed the issue whether epidemiology is a required basis of expert testimony concerning causation in a teratology case. Neither of the Fourth Circuit cases cited by Petitioner to suggest a conflict within

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[9] *Id.* at 132, 136, 139.

[10] *Id.* at 141.

[11] The material quoted by Petitioner as if it were from *Ambrosini* is actually from another case, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), which is not a teratology case.

[12] *Ambrosini*, 101 F.3d at 138, 140.

[13] *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349 (6th Cir. 1992).

[14] *Id.* at 1353-57.

the Fourth Circuit's own case law—*Westberry* and *Benedi*—are teratology cases. Thus, there would be no conflict in the Fourth Circuit's own case law even had the court of appeals in this case required that expert testimony in teratology cases be based in part on epidemiology.[15]

CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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June 25, 2004

[15] Petitioner's argument (at 20-21) that the "disparate decision" of the Florida Supreme Court in *Castillo* "cr[ies] out for intervention by this Court" to provide guidance and promote uniformity ignores the fact that *Castillo* was decided under the *Frye* standard while the decision in this case was guided by Rule 702 and the *Daubert* standard. Uniformity of decisions under *Frye* and under *Daubert* cannot be expected because of the differences in the two rules and thus, Petitioner's argument from *Castillo* does not support a writ of certiorari.